REMARKS

Applicant wishes to thank the Examiner for the consideration given this case to date. Applicant has had an opportunity to carefully consider the Examiner's action and in an effort to place the application in condition for allowance, or alternatively, to remove issues and present the claims in better form for consideration on appeal, Applicant has canceled claims 1-14 and 28-42, and has amended claims 15-27.

Applicant has addressed only the rejections pertaining to claims 15-27 and 43 below, in light of this amendment. Presently, claims 15-27 and 43 are pending. In light of the foregoing and the remarks below, Applicant respectfully submits that this Amendment after final should be entered and the instant claims passed to issuance.

THE EXAMINER'S ACTION

In the Office Action dated March 7, 2003, the previous rejections were maintained, specifically the Office:

rejected claim 43 under 35 U.S.C. § 112, first paragraph as setting forth new matter;

rejected claims 1-14 under 35 U.S.C. § 102(e) as being anticipated by Patel et al., U.S. Patent No. 6,309,663;

rejected claims 15-27 under 35 U.S.C. § 102(e) as being anticipated by Patel et al.;

rejected claims 28-41 under 35 U.S.C. § 102(b) as being anticipated by Bremer et al., U.S. Patent No. 5,643,874;

rejected claims 15-27 under 35 U.S.C. § 102(b) as being anticipated by Bremer et al., the '874 reference; and

rejected claims 28-42 under 35 U.S.C. § 103(a) as being unpatentable over Bremer et al. in view of Patel et al.

REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The Examiner rejected claim 43 under 35 U.S.C. 112, first paragraph as containing new matter (See Office Action dated 3/7/03, pg. 2, ¶ 5). Specifically, the Examiner took the position

that claim 43, which recites a method of administering a composition that "does not include a lipase inhibitor," is not supported by the specification.

Compliance with the written description requirement is a question of fact. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991). The purpose of the "written description" requirement is to explain how to "make and use", and to "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is for purposes of the 'written description' inquiry, whatever now is claimed." *Id.* at 1563-64, 19 U.S.P.Q.2d at 1117 (emphasis in original); *All Dental Prodx LLC v. Advantage Dental Prod. Inc.*, 64 U.S.P.Q.2d 1945, 1948 (Fed.Cir. 2002) (reasoning that language "fairly simple and intelligible, capable of being understood in the context of the patent specification...is thus reasonably clear [as to] what the invention is...[and] the specification need not describe the claimed subject matter in the same terms as used in the claims...."); *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570, 39 U.S.P.Q.2d 1895, 1904 (Fed. Cir. 1996) ("[T]he disclosure need only *reasonably* convey to persons skilled in the art that the inventor had possession of the subject matter in question.") (emphasis added).

In *Ex parte Parks*, the Examiner rejected the claims under 35 U.S.C. § 112, first paragraph as having a lack of adequate descriptive support because there was "no literal basis" for the claim limitation "in the absence of a catalyst." 30 U.S.P.Q.2d 1234, 1236 (Bd. Pat. App. & Interf. 1994). The Board reversed the Examiner, holding that the originally filed disclosure would have conveyed to one of ordinary skill in the art that the Applicant had possession of the concept of conducting the claimed process in the absence of a catalyst because of the examples in the specification. *Id.* The Board held that throughout the discussion "no mention is made of a catalyst," and therefore one of ordinary skill in the art would recognize that the reaction was conducted without a catalyst, thereby meeting the requirements of § 112. *Id.* 1236-37.

Similarly, Applicant has provided written support for claim 43 which contains the limitation that the composition does not include a lipase inhibitor by including examples of such a formulation. Applicant includes multiple examples of a composition of acarbose and a sustained release matrix, namely HPMC (See Spec. pg. 2, lns. 18-19, pg. 8, lns. 11-12). As described, such a composition does not contain a lipase inhibitor. In fact, there is no mention of

a lipase inhibitor. Based upon these examples, one of ordinary skill in the art would recognize that the composition contained acarbose and a sustained release matrix and did not contain a lipase inhibitor. As such, Applicant has conveyed with reasonable clarity that Applicant was in possession of the subject matter, thereby meeting the requirements of § 112 (¶ 1).

REJECTIONS UNDER 35 U.S.C. § 102(e)

The Examiner rejected claims 15-27 as being anticipated by Patel, U.S. Patent No. 6,309,663 (hereafter "Patel"). The Examiner contended that Patel discloses a composition comprising surfactants and a hydrophilic therapeutic agent, such as acarbose (See Office Action dated 7/9/02, pg. 3, ¶ 3).

1. The Amended Claims Cast in "Consisting Essentially of" Format are not Anticipated by Patel.

Applicant's amended claim 15 calls for a composition of acarbose and a sustained release matrix to form a mixture. As defined in the specification and recited in the claims, the sustained release matrix causes constant release of the acarbose over a period of time (See Spec. pg. 2, lns. 14-17) Patel does not teach that which is encompassed by c laims 15-27 because Patel does not disclose a combination of acarbose and a sustained release matrix, which necessarily causes constant release of acarbose in a mixture.

Applicant has amended the claims to recite a composition consisting essentially of acarbose and sustained release matrix. "By using the term 'consisting essentially of' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic novel properties of the invention. A consisting essentially of claim occupies the middle ground between closed claims that are written in a consisting of format and fully opened claims that are drafted in a comprising format." *PPG Industries v. Guardian Industries, Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998) (citing *In re Herz*, 537 F.2d 549 (CCPA 1976)).

In *BASF Corp. v. Eastman Chemical Co.*, claim 6 of BASF's patent claimed a process for the catalytic rearrangement of EB to DHF which "consists essentially of the rearrangement being

catalyzed by a system which contains components A and C from 60° to 200° C where A is an onium halide, which is substantially soluble in the reaction medium and C is a Lewis acid or elemental iodine with the provisio that at least one of the components A or C is an iodine." 56 U.S.P.Q.2d 1396; 1403 (D. Del. 1998). The court concluded that the phrase "consists essentially of" excludes the addition of any component B, a solublizer, because one of the basic and novel characteristics of claim 6 is that component A is intrinsically soluble. *Id* at 1404-05. Because it is intrinsically soluble, the court found that component B does not need to be added to make it soluble and the addition of component B, a solublizer, and would alter this inherent trait. *Id.*

In another case, a claim directed to electrically insulating glass "consisting essentially of" nine ingredients but not including sulfur or carbon was not anticipated by a reference disclosing an amber-colored glass with no electrical insulating properties containing sulfur and carbon . *In re De Lajarte* 337 F.2d 870, 873-74 (CCPA 1964). The court found that in showing that the claimed glass had the basic and novel properties of electrical insulation not possessed by the prior art, the Applicant met the burden of showing that the different composition could cause differences in the properties of the glass.

In light of the amendments, the claims call for a composition of acarbose and a sustained release matrix and any other component which does not alter the basic and novel characteristics of the composition. Patel discloses a composition comprising at least two surfactants and a hydrophilic therapeutic agent, such as acarbose (See Col. 4, lns. 1-5). Patel teaches that hydrophilic therapeutic agents inherently experience multiple barriers to absorption (See Col. 1, ln. 13-31). In order to overcome these inherent difficulties, Patel discloses a composition which includes an "absorption-enhancing agent" and the particular therapeutic agent. The absorption-enhancing agent, namely at least two surfactants, "enhances the rate, extent and/or consistency of bioabsorption of the hydrophilic therapeutic agents." (See Col. 4, lns. 54-58).

Patel's composition includes additional components including at least two surfactants. Applicant's claims exclude such additional components because the introduction of the at least two surfactants "materially affect the basic and novel characteristics" of the claimed invention, therefore Patel does not anticipate the instant claims. MPEP § 2111.03; *In re Herz*, 537 F.2d 549, 551-52 (CCPA 1976) (emphasis in original). By adding "at least two surfactants" to the

composition claimed by Applicant would materially alter the basic and novel characteristics of Applicant's claimed composition, namely "the rate, extent and/or consistency of bioabsorption" of the composition would be unexpectedly enhanced. As Applicant teaches, the novelty lies in the resulting constant and controlled release of acarbose for absorption in the small intestine. Altering the absorption of the composition necessarily alters the basic and novel characteristics of Applicant's composition (See Col. 4, lns. 57-58). As such, the claims are not anticipated by Patel et al. and the rejection has been overcome.

2. Patel Does Not Disclose a Sustained Release Matrix.

Additionally, it is respectfully submitted that although Patel discloses that the combination of two surfactants and a therapeutic agent may be "enteric coated" which relates to "a mixture of pharmaceutically acceptable excipients which is applied, combined with, mixed with or otherwise added to the hydrophilic therapeutic agent," this is only used to definitionally broaden the idea of a coating. (See Col. 38, lns. 53-57). However, this enteric coating is not sustained release matrix, which alters the rate and extent of release, but rather an excipient altering the location of the release of the agent. As Patel states, the enteric coating causes release of the therapeutic agent in the lower gastrointestinal tract. (See Col. 38, lns. 36-43). Additionally, Patel teaches that the delayed-release coating is pH-dependent. In contrast, Applicant's sustained release matrix is pH-independent. Patel does not disclose or suggest that the enteric coating is a sustained release matrix, nor does Patel teach or suggest acarbose "mixed with" a sustained release matrix.

Patel also discloses "a coated multiparticulate composition." (See Col. 38, lns. 12). However, Applicant has not claimed a "coated multiparticulate composition," but rather a composition of acarbose and a sustained release matrix. In addition, Patel does not disclose a sustained release matrix.

Patel also discloses that the "enteric coating" may be applied through aqueous dispersion. (See Col. 38, lns. 61-63). Again, it is respectfully submitted that Patel does not teach that the enteric coating is a sustained release matrix. Furthermore, Applicant has not claimed that the sustained release matrix is applied through an aqueous dispersion. In fact, the specification

teaches that acarbose and a sustained release matrix are preferably dry mixed (See Spec. pg. 7, lns. 5-6).

The composition disclosed by Patel necessarily involves an uneven, uncontrolled release of the therapeutic agent. As the coating of Patel dissolves, the composition is released, or essentially leaks out of the coating at an uneven, uncontrolled rate. This discontinuous dissolution causes spikes in the therapeutic concentration of the active ingredient in the patient. It is respectfully submitted that the Applicant's combination of acarbose and a sustained release matrix achieves a true sustained release of the composition. As defined in the specification, the sustained release matrix causes constant release of the acarbose over a predetermined period of time (See Spec. pg. 2, lns. 14-17). As embodied in claim 15, the composition provides a constant, controlled release of the formulation. Patel's composition of at least two surfactants and a therapeutic agent, such as acarbose, does not include a sustained release matrix, such that constant release of the composition is achieved. Furthermore, Applicant's composition is limited to the active ingredient, acarbose, and a sustained release matrix. In contrast, Patel's composition contains a therapeutic agent and at least two surfactants. As Patel discloses, the additional at least two surfactants materially alter the characteristics of the composition by causing increased absorption (See Col. 4, lns. 50-59). As such, it is respectfully submitted that claims are not anticipated by Patel et al. and the rejection has been overcome.

REJECTIONS UNDER 35 U.S.C. § 102(b)

The Examiner also reject ed claims 15-27 as being anticipated under 35 U.S.C. § 102(b), by Bremer et al., U.S. Patent No. 5,643,874. The Examiner stated that Bremer discloses a composition of glucosidase and/or amylase inhibitors in combination with a lipase inhibitor in the treatment of obesity (See Office Action dated 7/9/02, pg. 5, ¶ 5). The Examiner further asserted that because Applicant's have not claimed acarbose alone to stimulate weight loss, Bremer's disclosure does not teach away from Applicant's method of treating a patient to stimulate weight loss comprising administering an acarbose formulation to the patient (See Office Action dated 3/7/03, pg. 4, ¶ 12, pg. 6, ¶ 14).

As amended, Applicant has claimed a composition consisting essentially of acarbose and a sustained release matrix alone. Again, the language set forth in the amended claims excludes the presence of other ingredients that would change the novel and basic characteristics of the claimed composition. A lipase inhibitor is necessarily excluded because the addition of a lipase inhibitor to the claimed composition would materially alter the novel and basic characteristics of the claimed composition. As Bremer teaches, a lipase inhibitor causes inhibition of lipase (See Col. 4, lns. 19-23). Acarbose does not cause any inhibition of lipase. By adding a lipase inhibitor to the composition of acarbose and a sustained release matrix, the claimed composition would be materially altered by causing inhibition of lipase.

Furthermore, Bremer states that glucosidase and/or amylase inhibitors, *used in monotherapy* in combination with a reduction diet bring about "practically no weight loss," but that in combination with a lipase inhibitor does stimulate weight loss. (See Col. 4, lns 23-26). Applicant's composition, which lacks a lipase inhibitor, stimulates weight loss. Therefore, adding the additional component of a lipase inhibitor would alter this inherent trait. Since Bremer's composition includes a lipase inhibitor, it does not anticipate the instant claims.

Moreover, Bremer does not disclose a composition of acarbose and sustained release matrix. As the specification discloses, the sustained release matrix, which is uniformly mixed with acarbose, causes a constant, controlled release of the composition over a predetermined period of time and such release occurs in the lower gastrointestinal tract (See Spec. pg. 2, lns. 14-17). In contrast, the composition of Bremer which includes among other things, HPMC, only causes release and increased residence time in the stomach (See Col 6, Ex. D). Bremer's formulation as used in Example D did not result in a controlled, constant release of the formulation in the lower gastrointestinal tract.

Applicant submits Bremer does not teach the use of an acarbose and sustained release matrix composition. Applicant's disclosure states that a composition of acarbose and a sustained release matrix, in and of itself, will result in the stimulation of weight loss in a subject. Bremer clearly teaches away administering a composition of acarbose and no other active ingredients for stimulating weight loss (See Col. 4, lns. 23-26). Based on Bremer's disclosure, one of ordinary skill in the art would not expect that administering only a formulation of acarbose, as claimed by

Applicant, would stimulate weight loss. Furthermore, it is the combination of acarbose and a sustained release matrix which results in weight loss, since administration of acarbose alone does not result in weight loss. In light of the foregoing, Bremer does not anticipate the instant claims and Applicant respectfully submits that the rejection has been overcome.

Conclusion

In light of the foregoing, Applicant respectfully submits that claims 15-27 and 43 are patentable over the references of record and are thus in condition for allowance. Applicant respectfully requests an early indication thereof.

Respectfully submitted,

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